IN THE UNITED STATES PATENT OFFICE

Title:	Positive Wakeup Pharmaceutical Sleep System		
Applicant:	William J Ayala	Group:	4666
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REPLACEMENT PARAGRAPHS OF SPECIFICATION

Page 17, line 3 insert new paragraph as follows:

All content in the Examples, including formulations and test results, are hypothetical, but based on existing industry techniques as applied by the inventor's knowledge, experience, and extensive research of the literature.

Page 18, paragraph 2

For the presently favored embodiment, provision for a certain interval of delay, as well as issuance of the internal arousal stimulus is accomplished by the inner subsystem. The subsystem incorporates at least one subunit. Ordinarily, this involves a core-coat configuration. The subunit structure is based upon a core which includes one or more pharmaceutically active agent with appropriate excipients, completely encased in an inert polymeric coating layer. The core may include any appropriate conventional excipients known to the art, including gas-generating substances such as, but not restricted to, sodium bicarbonate and calcium carbonate couple with one or more mild acids such as citric acid and sodium dihydrogen phosphate. The coating constitutes an osmotic semi-permeable membrane, which is impenetrable by the drug, and although water-insoluble, is permeable to influx of water. This arrangement has been selected for its excellent ability to meet the objectives of independence from specific gastro-intestinal environments and precise delay without premature leakage.

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The basis of delayed-release operation for this embodiment is osmotic absorption of water over time through the semipermeable membrane. When a dosage unit is introduced to the gastro-intestinal (g.i.) tract, water vapor is drawn inwardly through the membrane layer of the subunit from the exterior environment. As the hydrophilic core material transforms into an osmotic solute, more water is imbibed into the subunit due to the osmotic gradient across the membrane. Time is consumed while the volume increases and an inner force is generated which distends and stresses the constitution of the polymeric layer. This process goes on until an area of the membrane encounters its moment of maximal elongation. At this point, structural integrity fails, marking the end of the delay phase. The bulb ruptures from inner pressure, creating large fissures, and the components of the core are positively and completely discharged to the g.i. tract. Such swelling will have advanced over a precalculated span of time, therefore completing coordination of a precise delay upon release. In application, stimulus and wakeup response are initiated upon absorption, and conclusion of the sleep interval is imminent. Preferably, after ingestion of the dosage, the membrane is progressively expanded by internal pressure in synchronous correlation with residence in the gastrointestinal tract until the membrane bursts, thereby accomplishing delayed release of the wakeup agent.

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Generally, the range for the overall lag, from the time of ingestion to the initiation of stimulus action, is approximately 5 to 9 hours and preferably about 5 to 7.5 hours. Concordantly, the length of the time segment between the prompt release of sleep-compatible substance and delivery of arousal agent, in basic embodiments, falls within about 4.5 to 8.5 hours. Optimally, the programmed delay falls between about 4 to 7 hours. One version for these ranges is contemplated wherein the planned interval of sleep is a nap. In this situation, the overall lag may run from 2 to 5.5 hours, based upon a programmed duration for the delay falling between about 1.5 and 4.5 hours. It should be noted, however, that these time lengths may vary by design to accommodate the individual needs of diverse classes of patients.